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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection ofin formation unless it displays a valid OMB control number. **Docket Number (Optional)** PRE-APPEAL BRIEF REQUEST FOR REVIEW S63.2-8920-US01 I hereby certify that this correspondence is being deposited with the Application Number United States Postal Service with sufficient postage as first class mail October 16, 2001 in an envelope addressed to "Mail Stop AF, Commissioner for 09/982052 Petents, P.O. Box 1450, Alexandria, VA 22313-1450" (37 CFR 1.8(a)) - November /5, 2005 First Named Inventor John Randby Art Unit Examiner Michael H. Thaler Typed or printed 3731 <u>Robin Peddieson</u> name Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. . The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. I am the applicant/inventor. assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. William E. Anderson Typed or printed name (Form PTQ/\$B/96) Х attorney or agent of record. 952<del>1</del>563-3008. . :: `` :"... 37766 Registration number Telephone number attorney or agent acting under 37 CFR 1.34. 2005 November 15, Registration number if acting under 37 CFR 1.34 Date NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

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Application No.: 09/982052 Filed: October 16, 2001

## REASONS FOR PRE-APPEAL REQUEST FOR REVIEW

In this case, a Final Office Action was issued on May 16, 2005. Applicant filed a response within two months of the issuance of the Final Office Action on July 14, 2005. As of yet, Applicant has not received an action in response to Applicant's response to the Final Office Action. However, it was communicated to Applicant by the Examiner on November 10, 2005, that an Advisory Action will be issued. As such, due to the fact that Applicant's sixth-month date is November 16, 2005, Applicant is filing this preappeal request for review without having the Advisory Action in hand to avoid abandonment. It is assumed, for the purposes of this request, that the arguments made in the Final Office Action are unchanged by the Advisory Action and, therefore, the comments made below are directed toward those arguments in the Final Office Action.

Applicant hereby requests that the Advisory Action to be issued in this case be overruled and that the case be remanded to the Examiner because the rejections, which are discussed below, are clearly in error and not justified. Since there is only one independent claim (claim 1) and the rejections of the dependent claims depend upon it, the remarks below are confined to that claim (claim 1). Claim 1 is as follows:

## A stent delivery system comprising: 1. (Previously presented)

a catheter comprising an expandable distal portion, having an outer diameter, constructed and arranged for expanding the outer diameter of said expandable distal portion from a contracted state to an expanded state;

a stent positioned around said distal portion of said catheter, said stent having a contracted condition and being expandable to an expanded condition, the stent being sized in said contracted condition to surround said expandable distal portion in its contracted state, said stent having a first end and a second end, wherein at least a portion of the stent may be positioned over a portion of said expandable portion of said catheter; and

a first sleeve in the region of said distal portion of said catheter positioned around said catheter, the first sleeve having a first end attached to said catheter, and being positionally fixed relative to the catheter, and a second end being about the expandable distal portion, wherein the expandable distal portion is movable within the second end relative to the second end, said second end of the first sleeve abutting the first end of the stent when the expandable distal portion is in its contracted state, such that the first sleeve and the stent do not overlap.

In the Final Office Action, claim 1 was rejected under 35 USC §102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Willard et al. (5,980,530). It is asserted in the action that Willard et al. disclose a catheter comprising a first sleeve 22 having a first end (the left end) attached to the catheter and a second end (the right end) being about a expandable distal portion 14, wherein the second end of the first sleeve abuts the first end of the stent when the an expandable distal portion 14 is in its contracted state. It is reasoned in the rejection that the "contracted state" of the expandable distal portion 14 is considered to be the state slightly contracted relative to the state shown in figure 2, wherein the right end of the first sleeve 22 inherently abuts the left end of the stent just as the sleeve slides off the outer surface of the stent. It is further asserted in the rejection that the term "contracted" is a relative term and does not require complete retraction of the balloon. Alternatively, it is asserted that it would have been obvious that the right end of the first sleeve 22 abuts the left end of the stent just as the sleeve slides off the outer surface of the stent since the sleeve contracts toward the balloon as it slides off the outer surface of the stent.

The rejection is in clear error because in the art of stent delivery systems the term "contracted state" is not a relative term as asserted in the rejection. Rather, in the context that it is being used here, it is widely considered to refer to the "delivery configuration" of the stent delivery system. That is the configuration the delivery system is in when it is inserted into the body and maneuvered to a target location. Willard et al., the cited reference, specifically states that Fig. 1 (which is attached for convenience sake) illustrates the balloon 14 in its "contracted state" (specifically stated at col. 3, lines 9-12). In the contracted state, it is clearly shown in Fig. 1 and stated in the specification that the

ends of the sleeves 22, 24, cover the ends of the stent 20 and do not abut them. At the point at which the sleeves slide off the stent, the balloon would be partially inflated or pressurized *from* its contracted state or delivery configuration.

It is well known in the art that the contracted state of a balloon is its non-pressurized state or delivery configuration that it is in when it is delivered to a target site and not in a partially expanded or pressurized state, which is asserted in the rejection. For the sleeves to slide off of the stent in Willard et al., the balloon must be pressurized and expanded from its delivery configuration or contracted state. It also would not be obvious to alter the length of the sleeves of Willard et al. when it clearly teaches that they are to be long enough to overlap the ends of the stent. Claim 1, as shown above, specifically requires that "the first sleeve and the stent do not overlap". Each and every element of the claim is not accounted for and the teachings of the cited reference and claim 1 are clearly distinguishable. One skilled in the art would not interpret the term "contracted state" in the manner being used in the rejection.

For the above reasons, the outstanding rejections were made in clear error and it is hereby requested that they be overturned and that the application be remanded to the Examiner for continued prosecution.

Respectfully Submitted,

VIDAS, ARRETT & STEINKRAUS, P.A.

Date: November 15, 2005

William E. Anderson Attorney Reg. No.: 37766